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Supreme Court of the United States
October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Brief *Amici Curiae* of Physicians, Scientists, and Historians of Science in Support of Petitioners.

BRIAN STUART KOUKOUTCHOS
Counsel of Record
485 Concord Avenue
Lexington, Massachusetts 02173
(617) 861-6001

GEORGE W. CONK
TULIPAN, GOLDMAN & CONK, P.C.
55 Washington Street
East Orange, New Jersey 07017
(201) 676-1744

PRISCILLA BUDEIRI
ARTHUR BRYANT
TRIAL LAWYERS FOR PUBLIC JUSTICE, P.C.
1625 Massachusetts Ave., N.W.
Suite 100
Washington, D.C. 20036
(202) 797-8600

December 2, 1992

Counsel for Amici

BATEMAN & SLADE, INC. BOSTON, MASSACHUSETTS

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BRIEF *AMICI CURIAE* OF RONALD BAYER, STEPHEN JAY GOULD, GERALD HOLTON, PETER INFANTE, PHILIP LANDRIGAN, EVERETT MENDELSOHN, ROBERT MORRIS, HERBERT NEEDLEMAN, DOROTHY NELKIN, WILLIAM NICHOLSON, KATHLEEN JOY PROPERT AND DAVID ROSNER IN SUPPORT OF PETITIONERS.

INTEREST OF *AMICI CURIAE*

Amici are physicians, practicing scientists, historians of science, and scholars of the sociology of science who express no opinion on the merits of the plaintiffs' case and who have no interest in the outcome of this lawsuit.[1] *Amici* appear in their own behalf to alert the Court to the grave misunderstanding of science on which the decision below is predicated — a misunderstanding that threatens the integrity and accuracy of every federal court proceeding which depends on opinion testimony from scientists. If federal juries are going to rely on expert scientific testimony in deciding cases, then federal judges must have a proper understanding of the nature of scientific inquiry and of how practicing scientists work. This in turn requires recognition of the fact that scientists often disagree, and that different analyses of the very same data can often yield different conclusions. The need to understand how the work of scientists may be used in courts of law even when those scientists disagree transcends the perspectives of the parties in this case — indeed, it transcends even the perspective of any particular class of litigation such as tort cases — and without their participation here, *amici* fear that this issue might not be fully ventilated before this Court.[2]

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[1] The qualifications of and positions held by *amici* are set forth in the appendix bound with this brief.

[2] Counsel for all parties have consented to the filing of this brief. Letters of consent have been filed with the Clerk.

SUMMARY OF ARGUMENT

The decision below adopts a rule of admissibility, derived from *Frye v. United States*, that is premised on a remarkable misunderstanding of the nature of scientific inquiry. The Ninth Circuit held that certain expert testimony from scientists of unchallenged qualifications was wholly inadmissible because the methods of research and analysis employed by those scientists were, supposedly, not "generally accepted" by what the court referred to, without further elaboration, as the "scientific community." Yet the Ninth Circuit did not even purport to investigate the scientific methodology in question, nor did it survey the "scientific community" to determine just what the "consensus" was. Instead, the court below examined the *conclusions* reached by plaintiffs' experts, and then blithely concluded that the methodology of these scientists' studies was "problematic" — and therefore *per se inadmissible* — simply because their analyses had not been published in a peer-reviewed journal and because they reached a conclusion that contradicted what the court deemed to be a significant body of opposing evidence.

Judgments based on scientific evidence, whether made in a laboratory or a courtroom, are undermined by a categorical refusal even to consider research or views that contradict someone's notion of the prevailing "consensus" of scientific opinion. Science progresses as much or more by the replacement of old views as by the gradual accumulation of incremental knowledge. Automatically rejecting dissenting views that challenge the conventional wisdom is a dangerous fallacy, for almost every generally accepted view was once deemed eccentric or heretical. Perpetuating the reign of a supposed scientific orthodoxy in this way, whether in a research laboratory or in a courtroom, is profoundly inimical to the search for truth. A categorical refusal even to examine and consider scientific evidence that conflicts with some ill-defined notion of majority opinion is a recipe for error in any forum.

Unable or unwilling to investigate scientific methodology and determine just what is orthodox and "generally accepted," the Ninth Circuit instead seized upon publication in a peer-reviewed scientific journal as the badge of respectability, the *sine qua non* of admissible "good science." The court thereby converted that editorial tool into something no scientist or journal editor ever meant it to be: a litmus test for scientific truth. This is not the way scientists work in their laboratories and symposia, and it is not the way that science should be used in the courtroom if the goal is to ensure the most accurate and valid judgments possible.

ARGUMENT

THE NINTH CIRCUIT'S RULE OF ADMISSIBILITY, DERIVED FROM *FRYE V. UNITED STATES*, IS PREMISED ON A FUNDAMENTAL MISUNDERSTANDING OF THE NATURE OF SCIENTIFIC INQUIRY, AND WILL FORCE TRIERS OF FACT TO MAKE DECISIONS WITHOUT ACCESS TO ALL RELEVANT EVIDENCE.

Expanding on the reasoning of *Frye v. United States*, 293 F.2d 1013 (D.C.Cir. 1923), the court below held that in order for a scientific opinion to be admissible, the methodology employed by the scientist to reach the opinion must meet "the essential requirements" imposed "by the scientific community." (A5).[3] Without reference to *any* authority drawn from the scientific community, the Ninth Circuit then served up the bald assertion that the "requirements" of that community include publication of the expert's study. (A5). It concluded that unless an expert scientific study reflects the "consensus"

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[3] Citations in this form refer to the appendices bound with the Petition for Writ of Certiorari.

of the pertinent field and has been published in a peer-reviewed journal, then it is not "good science" and is *per se* inadmissible in a federal court. (A5).

Although the courts below purported to determine the admissibility of plaintiffs' expert testimony by asking whether the methodology of the experts' studies was "a generally accepted scientific technique" (A4), it is plain from the face of their opinions that the courts were in fact interested only in deciding whether those experts' *conclusions* were generally accepted.

For example, with respect to one expert's reanalysis of previously compiled epidemiological data about Bendectin, the Court of Appeals did not even purport to investigate the soundness or professionalism of the expert's approach. Instead, it simply asserted, without reference to any authority drawn from the scientific community, that reanalysis is "generally accepted by the scientific community" only when it is subject to peer-review and published. (A4; *see also* A5).[4] In fact, reanalysis is generally accepted as a valid technique whether or not the specific reanalysis in question has been peer-reviewed and published. Indeed, the District Court noted without reservation or criticism that plaintiffs' epidemiologists and biostatisticians based their opinions "on techniques that are generally and reasonably relied upon by biometrists, epidemiologists and biostatisticians." (A13).

Nor did the courts below question the soundness, quality, or professionalism of the animal studies, *in vitro* studies, and pharmacological and toxicological research on which plaintiffs' experts relied. (A11-13) (District Court's review of evidence). Significantly, the qualifications of plaintiffs' expert

[4] The only authority cited was a single law review article. (A4).

scientific witnesses were not challenged by the defendant or by either court below.

Instead of directly evaluating the methodology of the research on which plaintiffs' experts relied, the Ninth Circuit began with those experts' conclusions and worked backwards. Thus, the Court of Appeals examined the *result* of one witness's reanalysis of epidemiological data — the same published data relied upon by the defendants' witness — and then opined that this reanalysis was "particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community." (A4). This "massive weight" — which obviously relates to the conclusions reached by the studies, rather than to their methodology — was thought to flow from the fact that "no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects." (A2).

While purporting to search for a "consensus" in the *scientific* community to justify its limits on the permissible scope of expert testimony, the Court of Appeals in fact searched only for a "consensus" in the *legal* community, by looking at how other courts have treated various forms of scientific evidence in Bendectin cases. Thus, the Ninth Circuit's ruling of inadmissibility turned *not* on the methodology of the underlying research, *nor* on the caliber and nature of the experts' analytical methods, *nor* even on the nature of some supposed "consensus" in the scientific community, but on the fact that these experts' analyses had not been published (A4, A5), and on the fact that their conclusions contradicted what the Ninth Circuit took to be the conventional wisdom. (A4).

This myopic mode of decision-making — which refuses even to consider research that is deemed to be at odds with the prevailing wisdom — strikes *amici* as an unsound basis on

which to predicate government action influenced by scientific testimony. As scientists, physicians, historians of science and sociologists of science who are members of the "scientific community," *amici* can assure the Court that this is not how scientists work in their pursuit of truth. *Amici* challenge the Ninth Circuit's premise that the only "good science" is that which is "generally accepted" and published in peer-reviewed journals, and reject the notion that scientific analysis and conclusions that might diverge from what a court deems the published "consensus" are so unreliable as to be wholly unworthy of consideration. The quality of a scientific approach or opinion depends on the strength of its factual premises and on the depth and consistency of its reasoning, not on its appearance in a particular journal or on its popularity among other scientists. Even if it were possible to determine the existence and character of a "consensus," which is itself a task fraught with difficulty, prevailing views and conventional wisdom have all too often been consigned to the dust heap of the history of science. If the purpose of the Federal Rules of Evidence is to enable the fact-finder to make the most informed decision possible, by providing the assistance of qualified experts who possess "scientific, technical or other specialized knowledge [that] will assist the trier of fact to understand the evidence or to determine a fact in issue," Fed.R.Evid. 702, then it would be a grave mistake to require that all scientific analysis be supported by a consensus and published in a particular form in order to be considered.

A. Scientific Inquiry, Like the Fact-Finding Process in the Law, is Undermined By a Categorical Refusal Even to Consider Views or Analysis That Challenge the Supposed Conventional Wisdom.

The Ninth Circuit's almost cursory conclusion that the only science worth considering is that which reflects some undefined "consensus" in the field is predicated on two fallacious assumptions about the nature of scientific inquiry.[5]

First, the court below assumes that science always progresses by the continuous accumulation of objective, irrefutable truths, which are gradually incorporated into a consensus reflected in the scientific literature. This is incorrect. "[A] new theory, however special its range of application, is seldom or never just an increment to what is already known. Its assimilation requires the reconstruction of prior theory and the reevaluation of prior fact, an intrinsically revolutionary process." Thomas Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 7 (2d ed. 1970). Thus, "[s]cience advances primarily by replacement, not by addition." Stephen Jay Gould, THE MISMEASURE OF MAN 322 (1981). The conventional scientific wisdom is as often a stumbling-block as a stepping-stone to better understanding. The English philosopher and scientist Roger Bacon recognized seven centuries ago that among the "very significant stumbling-blocks in the way of grasping the truth, which hinder every man however learned, [are] . . . unworthy authority, longstanding custom, [and] the feeling of the ignorant crowd." OPUS MAJUS (1267).

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[5] It is unsurprising that the Ninth Circuit's narrow concept of "good science" is so misguided, since in reaching its definition the court relied not on the experience of practicing scientists and historians of science, but exclusively on the authority of a single attorney. (A5)(citing P. Huber, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTHOUSE 228 (1991)).

The later philosopher and essayist Francis Bacon agreed that "men have been kept back as by a kind of enchantment from progress in the sciences by reverence for antiquity, by the authority of men counted great in philosophy, and then by general consent." NOVUM ORGANUM, Aphorism LXXXIV (1620). This is because "[t]he human understanding is no dry light, but receives infusion from the will and affections . . . . Therefore [a person] rejects . . . things not commonly believed, out of deference . . . " *Id.*, Aphorism XLIX. Science is a cultural, "socially embedded activity." Gould, *supra*, at 21. Facts are not unsullied, pristine bits of truth, because culture influences what we see and how we see it. *Id.* And theories "are not inexorable inductions from facts," but imaginative visions superimposed on those facts, and that imagination is itself an artifact of society and culture. *Id.* at 22. *See also* T. Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 35-36, 52, 64, 90, 153 (2d ed. 1970).

Because scientific conventions, like all other cultural conventions, resist change, "[i]t would be far more realistic to think of the history of science as a continuous, sometimes desperate struggle . . . ." Thomas Goldstein, THE DAWN OF MODERN SCIENCE 245 (1980). In the words of the Spanish philosopher Jose Ortega y Gasset, "[t]he man who discovers a new scientific truth has previously had to smash to atoms almost everything he had learnt, and arrives at the new truth with hands bloodstained from the slaughter of a thousand platitudes." THE REVOLT OF THE MASSES Ch.XIV (1930).

The Ninth Circuit's second fallacy is the assumption that scientific truths, once discovered, are complete, universal, immutable and eternal. The defendants have urged this Court that the expert testimony excluded here was inadmissible because it supposedly challenged "universally recognized scientific truths." Brief in Opposition at 2. Without passing judgment on the assertion that the safety of Bendectin rises to the level of a "universally recognized scientific truth," *amici*

would remind the Court of Alfred North Whitehead's dictum that "[t]here are no whole truths; all truths are half-truths. It is trying to treat them as whole truths that plays the devil." DIALOGUES 16 (1916).[6]

With respect to epidemiology in particular, the eminent biostatistician, Sir Austin Bradford Hill, has cautioned that "we can[not] usefully lay down some hard-and-fast rules of evidence that must be obeyed before we can accept cause and effect," because "[a]ll scientific work is incomplete — whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer on us a freedom to ignore the knowledge we already have, or to postpone action that it appears to demand at a given time." Hill, *The Environment and Disease: Association or Causation?*, 58 PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE 295, 299-300 (1965). As the editor of the JOURNAL OF THE AMERICAN PUBLIC HEALTH ASSOCIATION has pointed out, "conclusiveness in inferring causality — in epidemiology as with all studies of free-living human beings — is a desire more often than an accomplishment." Susser, *Rules of Inference in Epidemiology*, 6 REGULATORY TOXICOLOGY AND PHARMACOLOGY 116, 127 (1986). As a consequence, those who seek in science the immutable truth they find lacking in the law are apt to be disappointed:

> One notable similarity [between law and epidemiology] is the dependence of both fields upon subjective judgments.
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[6] *See also* I RESPONSIBLE SCIENCE: ENSURING THE INTEGRITY OF THE RESEARCH PROCESS 38 (Nat'l Academy of Sciences) (1992) ("Although its goal is to approach true explanations as closely as possible, [science's] investigators claim no final or permanent explanatory truths. Science changes. It evolves."),

> In the end, a quality which lawyers should understand better than any — judiciousness — matters more than any. Scientists use both deductive and inductive inference to sustain the momentum of a continuing process of research. . . . The courts of law, and the courts of application, use inference to reach decisions about what action to take. Those decisions often cannot rest on certitudes, most especially when population risks are converted into individual risks.

Id. at 116, 128. *See generally,* M. Susser, CAUSAL THINKING IN THE HEALTH SCIENCES: CONCEPTS AND STRATEGIES IN EPIDEMIOLOGY (1973).

These reservations about scientific truth and certainty plainly went unheeded in the court below. Consider, for example, the Ninth Circuit's cursory dismissal of the technique of reanalysis of epidemiological data. (*See* A5). To take the data compiled or used in a previous study and to subject it to fresh calculation and statistical analysis is an unremarkable step, akin to auditing a previously completed financial report or to submitting medical records and complex test results to another physician to obtain a second opinion.[7] Indeed, the District Court itself characterized the reanalysis performed in this case as "'the methodology that is generally and reasonably relied upon by epidemiologists to analyze, study and interpret data that has been collected.'" (A12).[8]

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[7] *See also* Gould, THE MISMEASURE OF MAN, *supra* (discussing history of numerous reanalyses of IQ data compiled by early intelligence researchers, which uncovered many fatal errors, some egregious and some subtle).

[8] The District Court's objection to these studies seems to have been based not on their methodology, but solely on the fact that they were not published in a peer-reviewed journal. (A14-15). *See also* A4-5 (same position taken by Ninth Circuit). This issue is dealt with below in Part B.

Without delving into the possible virtues or limitations of this particular epidemiological tool, we point out that much if not most advancement in science comes from looking at the same old facts in a different way. Science "lies not in discovering facts, but in discovering new ways of thinking about them." A.Bragg, *The Atom,* in THE HISTORY OF SCIENCE 167 (1948). "In a growing research discipline, inquiry is directed . . . to the discovery of new patterns of explanation." N. Hanson, PATTERNS OF DISCOVERY 2 (1958). "The paradigm observer is . . . the man who sees in familiar objects what no one else has seen before." *Id.* at 30. *See also* Kuhn, *supra*, at 111.

In defending the decision below, the respondents cling nevertheless to a strangely idealized notion of scientific inquiry, arguing that the testimony of plaintiffs' experts must be ruled inadmissible because it contradicts a huge body of evidence and is therefore nothing less than "*heresy.*" Brief in Opposition at 1, 3 (emphasis added). The use of such a term, in this century, to characterize testimony by reputable scientists of unchallenged qualifications, is truly astonishing. This approach, which was embraced by the Ninth Circuit, would enshrine a court's notion of consensus or majority opinion as scientific orthodoxy and silence all dissenting voices. The rule of orthodoxy may have a place in theology, but there is no place for dogma in science.[9]

To begin with, there is the vexing problem of deciding precisely what the orthodox position is. Scientific disciplines have neither pontiffs to determine official positions nor papal encyclicals to promulgate them. The Ninth Circuit relies on notions of "general acceptance" and "consensus" (A5), but

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[9] Joseph Priestly, the 18th century chemist who discovered oxygen, reflected on the dangers of conventional wisdom in his MEMOIRS, and quoted William Warburton, the Bishop of Gloucester: "Orthodoxy is *my* doxy; heterodoxy is another man's doxy." Vol. I at 572.

these unelaborated formulations beg more questions that they answer.[10]

For example, here the Ninth Circuit defined the "consensus" of the "scientific community" — on the issue of what evidence is pertinent to evaluating Bendectin's role in birth defects — entirely in terms of "published epidemiological stud[ies]" (A2), without regard to a wealth of evidence drawn from the fields of teratology, pharmacology, toxicology, pathology and clinical medicine. (A3; *see also* A13-14). The court held that no jury should even be allowed to consider this other larger, more diversified body of evidence. Yet epidemiologists themselves recognize that the "epidemiologist needs the contributions of many other disciplines in order to pursue his own." B. MacMahon & T. Pugh, EPIDEMIOLOGY: PRINCIPLES AND METHODS 15 (1970).[11] This is why federal public health authorities, including the Environmental Protection Agency and the Occupational Safety and Health Administration, make a policy of considering and relying on human, animal and laboratory studies in addition to statistical epidemiological evidence, which those agencies deem incomplete.[12]

[10] The Ninth Circuit's embrace of publication in peer-reviewed journals as the badge of orthodoxy will be discussed below in Part B.

[11] "While epidemiologic information is at times derived from a much wider spectrum of biologic and medical disciplines, these three — clinical medicine, pathology and biostatistics — have almost universal application in epidemiology. Indeed, epidemiology may be thought of as the joint application of the three in search for further understanding of disease etiology." MacMahon and Pugh, *supra*, at 16. *See also* Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, 1 COURTS, HEALTH SCIENCE AND THE LAW 374 (1991).

[12] *See, e.g.*, Environmental Protection Agency, Final Guidelines for Developmental Toxicity Risk Assessment, 56 FED. REG. 63798, 63799 (1991) ("Hazard identification/dose-response evaluation involves *examining all available experimental animal and human data* . . . to determine if an agent causes developmental toxicity") (emphasis added); EPA, Proposed Guidelines for Assessing Female Reproductive Risk, 53 FED. REG. 24834, 24836 (1988)(EPA consistently relies on "evaluation of *toxicological data from humans and experimental animals*" in assessing reproductive and developmental risks) (emphasis added); Occupational Safety and Health Administration, Final Standard for Occupational Exposure to Ethylene Oxide, 49 FED. REG. 25734, 25743 (1984) (OSHA ruling rested on a "*comprehensive* review of the scientific evidence . . . based on information from *many investigations in several species of experimental animals* . . . as well as positive results from several *human studies*") (emphasis added); OSHA, Final Rule for Identification, Classification and Regulation of Potential Occupational Carcinogens, 45 FED. REG. 5002, 5040-59 (1980) ("non-positive" epidemiological data "will rarely provide evidence to offset scientifically evaluated positive results . . . observed either from *other human studies or from experimental studies in test animals*") (emphasis added).

Epidemiology at best establishes a statistical probability that a particular chemical agent causes a particular effect, but the absence of such a statistical relationship does not prove the absence of a causal link.[13] Statistics alone cannot prove causality, but can at most establish correlations, which are merely suggestive of causation. Other disciplines focus on the causal mechanism itself by examining the chemical and biological processes that may lead to an injury. It strikes *amici* as more than passing strange, for example, for the courts below to have excluded testimony based on teratological research — which deals with the development of biological malformations — when the issue is whether a drug causes birth defects. One's concept of "general acceptance" or majority opinion in the "scientific community" thus turns on the way in which one defines the "community" at the outset.

Some courts have rejected the *Frye* approach precisely "because the general acceptance test was too vague and malleable to yield consistent results, and because its nose-counting emphasis often led to the exclusion of helpful evidence in contradiction to the spirit of the Federal Rules of

[13] "A high-quality negative epidemiological study, while useful, cannot prove the absence of an association. . . ." Office of Science and Technology Policy, Chemical Carcinogens: A Review of the Science and its Associated Principles, 50 FED. REG. 10372, 10378 (1985).

Evidence." *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1990).[14] Which noses would one count? If the scientist whose testimony is in question is a qualified expert, why wouldn't her voice count and suffice to destroy "consensus"? How many supposed "dissenters" does it take to negate consensus? This quandary may suggest why Congress enacted Fed.R.Evid. 702, whose requirements for "Testimony by Experts" mention no role for the federal judiciary in determining scientific consensus or checking for peer-reviewed publication as prerequisites to admissibility.

More importantly, the exclusion of scientific testimony that the respondent deems "heresy" is inimical to the search for truth. Advancement in scientific understanding frequently comes from what was once denounced by many as unorthodox. Indeed, as Thomas Huxley once remarked, "[e]xtinguished theologians lie about the cradle of every science as the strangled snakes beside that of Hercules." DARWINIANA. THE ORIGIN OF SPECIES (1860). Columbus was scorned as a renegade geographer. *See* Samuel Eliot Morison, ADMIRAL OF THE OCEAN SEAS (1940). Galileo was persecuted by the Inquisition for challenging the geocentric orthodoxy promoted by the Aristotelian scientists who dominated the academies and universities. *See* H. Kearny, SCIENCE AND CHANGE: 1500-1700 146-49 (1971).[15]

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[14] *See also State v. Williams*, 446 N.E.2d 444, 448 (Ohio 1983) (rejecting *Frye* because there is no wisdom "in scientific nose-counting for the purpose of deciding whether evidence based in newly ascertained or applied scientific principles is admissible.").

[15] The rule of scientific orthodoxy that the Ninth Circuit and respondent would engraft onto the Federal Rules of Evidence is no longer in vogue even in theological circles: the Vatican formally rehabilitated Galileo and renounced its four centuries of condemnation of his ideas on October 31, 1992. *See* N.Y. Times, Oct. 31, 1992, at A1, col. 1.

The phenomenon of yesterday's heresy becoming tomorrow's conventional wisdom is as current as the morning newspaper. For example, on November 17, 1992, the *New York Times* reported the discovery that plants, even though they lack nerve tissue, use electrical signals to alert their defense systems against threats such as grazing caterpillars. N.Y. Times, Nov. 17, 1992, at C1, col. 2 (discussing revelations in the Nov. 5, 1992 issue of NATURE). This discovery "jolted" the scientific community because "the study of electrical signaling [in plants] ha[d] long been shunned" by "most serious scientists." *Id.* "Things got so bad that even by suggesting that an electrical message could be an important signal in plant cell communication a scientist could open himself to ridicule. 'Plant electrophysiology was squelched,' said Dr. Pickard. 'It was reduced to the level of spoon bending.'" *Id.* at C13, col.1.[16]

These examples and a thousand more underscore the wisdom of Bertrand Russell's "Seventh Commandment": "Do not fear to be eccentric in opinion, for every opinion now accepted was once eccentric." But the decision below is in fact even more dangerous than this suggests, for there was nothing "eccentric" about the reanalysis of epidemiological data or about the toxicological and pharmacological methodologies relied upon by the scientists whose testimony was excluded here. Neither court below purported to find anything unsound or unprofessional in the work of plaintiffs' experts: these research techniques were deemed "problematic" because of the supposed "massive weight of the original published studies supporting the defendant's position." (A4).

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[16] Mainstream plant researchers had become "enamored instead with chemical messengers, or hormones," and spent decades seeking in vain to isolate hormonal messengers that they had postulated and even named, while ridiculing the possibility of electrical communication. N.Y. Times, Nov. 17, 1992, at C13 col. 1. "'People have been trying to force a hormones explanation on everything,'" said Dr. Eric Davies, professor of biology at the University of Nebraska. *Id.* at C13, col. 3.

Testimony based on such research may, of course, ultimately be rejected in favor of conflicting evidence. But in scientific inquiry, such a rejection should be a deliberative determination that the rejected view is incorrect, *not* a threshold assumption that the view is *per se* unworthy of consideration simply because it does not concur with someone's idea of the majority position.

Indeed, we would think that the approach taken by the Ninth Circuit and promoted by the respondent is inimical to the search for truth in *any* discipline, not just in science. When a court is confronted by a body of legal scholarship, does it automatically refuse to consider the arguments and views of scholars whose position disagrees with the majority view in academe, or whose arguments are presented in an *amicus* brief rather than in a previously published law review article? When this Court must resolve a question of law on which the Courts of Appeals are divided 10 to 2, does it automatically dismiss the holdings of the courts in the minority without weighing their analysis? If a jury is asked to decide a question of fact on which qualified scientific testimony would be of assistance, we believe that the search for truth would be aided by allowing the jury to consider — as a practicing scientist would — *all* of the relevant evidence, not just that which a particular judge deems to reflect the consensus of scientific opinion.

B. The Ninth Circuit's Elevation of Publication in Peer-Reviewed Journals To The *Sine Qua Non* of Admissible "Good Science" Is Insupportable.

The Ninth Circuit's test for whether scientific research meets its admissibility standards of "general acceptance" and "consensus" ultimately boils down to a requirement that the study or research on which a scientist would base her opinion

have been published in a peer-reviewed journal. (A4-5). But the appearance of a study in a peer-reviewed journal does not necessarily mean that the study is generally accepted or even sound. Conversely, the fact that a study has not been published in a peer-reviewed journal does not mean that the study and any opinion based thereon are unreliable and would be of no help in resolving a question of fact.

The peer review process that precedes publication in many scientific journals is valuable, to be sure, but the Ninth Circuit is confused about the purpose and limits of that process. Peer review is a vital editorial tool whose "main functions," in the words of Dr. Arnold S. Relman, then editor-in-chief of the New England Journal of Medicine, are "to improve the quality of what is published" and "to help editors decide what they want to publish in their journals." L.A. Times, May 22, 1989, Pt. II, at 3 col. 1. The Ninth Circuit has made a fetish of publication, even though peer review takes place in many fora within the scientific community other than journals: peer review of papers submitted for presentation at conferences and meetings; review of grant applications; review by advisory committees. But "the peer review process is 'not meant to determine ultimate truth or falsity.'" *Ibid.* (quoting Dr. Relman, *supra*). As a former editor of the Journal of the American Medical Association has remarked, "[p]eer review is far from being a 'perfect sausage machine for grinding out the truth.' . . . 'Just because peer review is about a review of scientific data doesn't mean that it is itself a scientific process.'" *Id.* (quoting Elizabeth Knoll).[17]

Whether a particular scientist's research has been published in a peer-reviewed journal may be relevant to how much

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[17] *See generally* D. Chubin & E. Hackett, Peerless Science: Peer Review and U.S. Science Policy (1990) (discussing inherent limitations in peer review process); S. Harnad, ed., Peer Commentary on Peer Review: A Case Study in Scientific Quality Control (1982) (same).

weight the study is accorded by other scientists or by a government decision-maker, be it a civil jury or a regulatory agency. But the Ninth Circuit has made peer review into something it never claimed to be: a talisman of truth. It is unsurprising that the court below cites no scientific authority whatsoever for the outlandish proposition that unpublished studies are *per se* unreliable and unworthy of any consideration.[18] For medical experts routinely rely on the unpublished (and sometimes even unwritten) observations and opinions of other experts in diagnosing, treating, and determining the cause of disease, just as research scientists rely on the as-yet unpublished work of their colleagues.

Moreover, federal regulations expressly authorize federal regulatory agencies to rely on unpublished scientific research in determining health hazards and in crafting safety standards to protect the public. Regulations promulgated under the Toxic Substances Control Act require manufacturers to submit to the Environmental Protection Agency lists of *unpublished* health and safety studies regarding toxic substances contained in their products, in order to assist the agency in assessing the health risks posed by the products. 40 C.F.R. §716.35(3), (4). The Department of Agriculture requires that petitioners seeking reclassification of a genetically-altered plant as a non-pest submit "copies of *unpublished* studies, or data from tests performed." 7 C.F.R. §340.4(b) (emphasis added). These regulations reflect an understanding that the adoption of federal standards protecting the public health "cannot be postponed because definitive medical or scientific evidence is not currently available." 43 FED.REG. No. 53 11514 (Mar. 17, 1978). Such pressing and important decisions must be based on "the best available evidence" including, if necessary, unpublished data and studies. *Id.*

[18] The only authority cited by the court below was a single, ten-year-old law review article. (*See* A4).

The Ninth Circuit has set a daunting task for federal judges by mandating that they apply a vague "general acceptance" standard to screen the testimony of all qualified scientific experts before admitting their testimony to a jury.[19] It therefore comes as no surprise that the court below seized upon what it apparently took to be a quick and easy "Good Housekeeping Seal of Approval" for the scientific community — publication in a peer-reviewed journal. "Our society often wants to see peer review as a mechanical certification of truth for which no one has to take responsibility. No such mechanism is conceivable." J. Schlefer, *Truth, Beauty, and Peer Review*, TECHNOLOGY REVIEW, Oct. 1990, at 5.

[19] A different government attempt to apply a general acceptance standard to the scientific community illustrates the dangers and difficulty of automatically screening out scientific practices that supposedly depart from the norm. The Office of Scientific Integrity of the National Institutes of Health promulgated rules that defined scientific "misconduct" to include all "'practices that deviate from those that are commonly accepted within the scientific community.'" Wash. Post, March 20, 1992, at A24, col. 1 (quoting the OSI rule). The breadth and vagueness of this standard quickly provoked plans for amendment and revision. "As Dr. [Bernadine] Healy [director of the National Institutes of Health] has pointed out, this [community standard] would have implicated even the discoverer of penicillin, who serendipitously found good uses for bacteria growing in a contaminated lab dish." *Id.*

CONCLUSION

Although the "general acceptance" limitation on the admission of scientific evidence may have been intended to promote the ascertainment of truth and the achievement of justice in federal trials, *amici* believe that its application would have precisely the opposite effect. A jury, like a scientist, cannot reach the most accurate possible judgment on a scientific question if it is denied access to the relevant analysis of qualified scientists, simply because their studies have not yet been published or do not reflect some court's notion of what is generally accepted in the particular "scientific community" defined by that court. Decision-makers forced to wear such arbitrary blinders will stumble and take many unnecessary and avoidable falls. The Ninth Circuit's rule is predicated on a gross misunderstanding of scientific inquiry, and *Amici* therefore urge this Court to reverse the judgment below.

Respectfully submitted,

BRIAN STUART KOUKOUTCHOS
Counsel of Record
485 Concord Avenue
Lexington, Massachusetts 02173
(617) 861-6001

PRISCILLA BUDEIRI
ARTHUR BRYANT
TRIAL LAWYERS FOR PUBLIC JUSTICE, P.C.
1625 Massachusetts Ave., N.W.
Suite 100
Washington, D.C. 20036
(202) 797-8600

GEORGE W. CONK
TULIPAN, GOLDMAN & CONK, P.C.
55 Washington Street
East Orange, New Jersey 07017
(201) 676-1744

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APPENDIX

IDENTIFICATION OF AMICI CURIAE

RONALD BAYER is a Professor at Columbia University, Division of Sociomedical Sciences, School of Public Health. His interests center on questions of justice and health care, occupational health, and controversies in science and technology. He is currently a consultant for the World Health Organization's Global Programme on AIDS, and the Editor on Public Policy of ATIN (Abstracts and Critical Comments from Current AIDS Literature). He is on the Editorial Boards of the JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES, AIDS PATIENT CARE, and the AIDS POLICY JOURNAL. His book PRIVATE ACTS, SOCIAL CONSEQUENCES: AIDS AND THE POLITICS OF PUBLIC HEALTH (1989) has received numerous awards.

STEPHEN JAY GOULD is Alexander Agassiz Professor of Zoology, Professor of Geology, and Professor of the History of Science at Harvard University. He is also Curator of Invertebrate Paleontology in the Museum of Comparative Zoology. He is a Fellow of the American Association for the Advancement of Science, the American Academy of Arts and Sciences, and the National Academy of Sciences. He is on the editorial board of SCIENCE and has served on the editorial boards of several other journals. He is the recipient of several dozen academic medals, awards and prizes, including one of the first MacArthur Foundation Prize Fellowships. His numerous books on science and the history of science have garnered many awards, including the National Book Award and the National Book Critics Circle Award.

GERALD HOLTON is Mallinckrodt Professor of Physics and Professor of the History of Science at Harvard University. He has been Secretary of the American Academy of Arts and Sciences and was the Founding Editor of the Academy's journal, DAEDALUS. He has served on the Board of Directors of the American Association for the Advancement of Science, as President of the History of Science Society, and as Chairman of the U.S. National Commission on the History and Philosophy of Science. His numerous books include THE ADVANCEMENT OF SCIENCE, AND ITS BURDENS (1986), LIMITS OF SCIENTIFIC INQUIRY (1979), and SCIENCE AND CULTURE (1965).

PETER F. INFANTE holds a doctorate in epidemiology and a Doctor of Dental Surgery. He has worked as an epidemiologist for the Centers for Disease Control, conducting epidemiologic investigations to determine associations between exposure to toxic substances and cancer, pregnancy outcome, and other chronic disabling conditions. He has held key positions involving the review of health standards based on risk assessments and epidemiologic, toxicologic, and industrial hygiene data for the last nine years. Prior to that, Dr. Infante had major responsibility for the classification of carcinogenic substances and the establishment of the priority for their regulation. He is a Fellow of the American College of Epidemiology, and a member of other organizations related to occupational and environmental health. His current research interests are in occupationally related disease. He has over 80 publications in peer-reviewed journals.

PHILIP LANDRIGAN is the Ethel H. Wise Professor of Community Medicine at Mount Sinai School of Medicine in New York, where he is Chair of the Department of Community Medicine and Director of the Division of Environmental and Occupational Medicine. He is Editor-in-Chief of the AMERICAN JOURNAL OF INDUSTRIAL MEDICINE and ENVIRONMENTAL RESEARCH. He is Consulting Editor of ARCHIVES OF

ENVIRONMENTAL HEALTH and on the Editorial Board of the AMERICAN JOURNAL OF PUBLIC HEALTH. He has been honored by the Institute of Medicine, National Academy of Sciences and received the Meritorious Service Medal from the U.S Public Health Service.

EVERETT MENDELSOHN is Professor of the History of Science at Harvard University. He has been Vice President of the American Association for the Advancement of Science and has been on the editorial board of SCIENCE, its official journal. He has served on the Council of the History of Science Society and been President of the International Council for Science Policy Studies. He is a member of the American Association for the History of Medicine and an Editor of the JOURNAL OF THE HISTORY OF BIOLOGY. He has served on the National Academy of Sciences Committee on Life Sciences and Social Policy. His more than 60 published works include the books HUMAN ASPECTS OF BIOMEDICAL INNOVATION (1971) and THE SOCIAL PRODUCTION OF SCIENTIFIC KNOWLEDGE (1977).

ROBERT MORRIS is a physician who also holds a Ph.D. in Environmental Engineering and an M.S. in Biostatistics. He is an Assistant Professor in the Division of Epidemiology and Biostatistics at the Medical College of Wisconsin, Milwaukee. He has served, among other advisory and academic positions, as visiting scientist to the Harvard University School of Public Health and expert adviser to the National Research Council Committee on Environmental Epidemiology.

HERBERT NEEDLEMAN is Professor of Child Psychiatry and Pediatrics at the University of Pittsburgh School of Medicine. His pioneering research on the health effects of environmental lead on children became the basis for numerous public health policies, including the decision to eliminate lead from gasoline. His lead studies have become the model for

similar environmental health studies around the world. For his research, he has been honored with the First Scientific Studies Award of the Association for Children with Learning Disabilities, The Sarah Poiley Medal of the New Academy of Sciences, the Charles Dana Award for Pioneering Achievement in Public Health, and has been elected to the Institute of Medicine of the National Academy of Sciences.

DOROTHY NELKIN is a University Professor at New York University, where she teaches in the Department of Sociology and the School of Law. Her scholarship focuses on the public policies concerning science and medicine. She has served on the Board of Directors of the American Association for the Advancement of Science, on the National Academy of Sciences (NAS) Study Committee on Decision-Making in Applying Advances in Biology and Technology to Health, and on the Biotechnology Advisory Panel of the Congressional Office of Technology Assessment. She is the author or co-author of more than 170 published works, including the books SCIENCE AS INTELLECTUAL PROPERTY: WHO CONTROLS SCIENTIFIC RESEARCH? (1984), DANGEROUS DIAGNOSTICS: THE SOCIAL POWER OF BIOLOGICAL INFORMATION (1989), and CONTROVERSY: THE POLITICS OF TECHNICAL DECISIONS (3d rev.ed. 1991).

WILLIAM NICHOLSON is a Professor at the Mount Sinai School of Medicine of the City University of New York. His work at Mount Sinai has included direction of industrial hygiene studies, the development and use of analytical techniques for measurement of pollutants in various samples, the conduct of epidemiological studies on occupational cohorts, and the use of statistical analyses to establish, when possible, the dosage and time dependence of disease. Dr. Nicholson is an Advisory Editor of ENVIRONMENTAL RESEARCH, Assistant Editor of AMERICAN JOURNAL OF INDUSTRIAL MEDICINE, and he is on the Editorial Board of TOXICOLOGY AND INDUSTRIAL HEALTH.

KATHLEEN JOY PROPERT has degrees in biology and a doctorate in biostatistics. She is Assistant Professor of Biostatistics at the Harvard School of Public Health. She has published more than 40 articles in peer-reviewed journals. Much of her work has focused on design and evaluation of clinical trials of cancer therapies and treatments for pediatric HIV infection. She has performed peer reviews for CANCER TREATMENT REPORTS, BIOMETRICS, and the JOURNAL OF THE AMERICAN STATISTICAL ASSOCIATION.

DAVID ROSNER is a Professor of History at Baruch College and CUNY Graduate Center Doctoral Faculty, and an Adjunct Professor in the Department of Community Medicine at the Mount Sinai School of Medicine. In addition to his academic training in history, he holds an M.S. in Public Health. His awards include the Presidential Excellence Award for Distinguished Scholarship, Baruch College, 1992.